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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,033	12/04/2003	Stephen F. Badylak	3220-73985	8358

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EXAMINER	
SCHUBERG, LAURA J	

ART UNIT	PAPER NUMBER
1657	

NOTIFICATION DATE	DELIVERY MODE
10/16/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

indocket@btlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/728,033	BADYLAK, STEPHEN F.	
	Examiner	Art Unit	
	Laura Schuberg	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/2/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/02/2009 has been entered.

Claims 1-16 are currently pending.

Previous Rejections

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 10/02/2009 has been entered and considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Badylak (WO 98/25637) in view of Patel et al (US 5,955,110), Butler (WO 03/084410) and Oliver et al (US 4,399,123).

Amended claim 1 is drawn to a method for inducing the repair of damaged or diseased body wall tissues comprising the steps of preparing a graft composition comprising basement membrane of a warm-blooded vertebrate by removing endogenous cells, DNA and endotoxins from the graft; wherein the graft is administered to a patient in an amount effective to induce repair, wherein the body wall tissue

comprises a multilaminate, stratified structure comprising different tissue types including connective tissue, skeletal muscle, adipose tissue, epidermal tissue and the serous lining of the body wall cavity, and wherein the graft composition comprises a glycoprotein.

Dependent claims include the site of repair, wherein the graft is multi-layered, thickness of the layers, format of the layers, administration type and form, sterilization of the graft, addition of growth factors, and seeding with exogenous cells.

Badylak ('637) teaches the use of tissue graft composition comprising liver basement membranes of a warm-blooded vertebrate for the repair of damaged or diseased tissues (page 2 lines 1-6). The preparation involves the removal of cells and cellular components from the liver tissue (page 3 lines 3-32) and since this includes the same method steps as taught in the instant application for the removal of DNA and endotoxins (page 4 of the specification) this reference process will also remove DNA and endotoxins as well (page 3 lines 3-32). The graft composition can be implanted or fluidized and injected into a host to contact damaged or defective tissues and induce repair or replacement of the tissues (page 2 lines 6-8). Wherein the composition is in the form of a powder (page 4 line 22), sheet (patch) or gel (page 10 lines 20-21) is taught as well as wherein the composition is in a multilayered configuration (page 6 line 31) with sheets or strips having a thickness of up to about 500 μ (page 17 line 14). Sterilization of the composition by peracetic acid is taught as most preferred (page 5 lines 20-28). The composition has a honeycomb-like structure (page 10 lines 24-25) and this is interpreted as perforated. The reference includes wherein growth factors and

glycoproteins that facilitate cellular proliferation are added to the composition (page 11 lines 16-20) as well as the seeding with various exogenous cell types (page 12 lines 20-28) for the same reasons as described by Applicant's specification (page 13).

In addition, Badylak ('637) teaches that basement membrane prepared from liver tissue of warm-blooded vertebrates exhibit certain mechanical and biotropic properties similar to that which had been reported for intestinal submucosal tissue. The reference also states that liver basement membrane can be substituted in most, if not all, of the applications previously reported for intestinal submucosa, including enhancing wound healing, promoting endogenous tissue growth, stimulating cell proliferation and inducing cell differentiation (page 1 lines 16-24). These applications would all be required for the repair of the body wall. Wherein the construct is taught to have multiple layers at the opposite ends (thus forming a heterolaminate construct) to provide reinforcement for attachment to physiological structures such as bone, tendon, ligament, cartilage and muscle (page 6 line 32- page 7 line 4) is also taught to be an optional embodiment since the liver basement graft composition can be formed in a variety of shapes and configurations (page 6 line 28).

Badylak ('637) does not specifically teach wherein the body wall tissue to be repaired comprises the abdominal wall or wherein the graft composition is formed as a multilayered homolaminate construct.

Oliver et al teach a method wherein basement membrane is used various branches of surgery for the treatment of hernias (column 1 lines 55-66 and column 5 lines 60-62).

Butler teaches that basement membrane is a suitable material for repair of body wall tissues such as hernias (paragraphs 16, 21, 76-84, on pages 8, 10, 30-33).

Patel teaches a multilayered submucosal graft construct for use in hernia repair, gastroschisis repair (congenital stomach defects) and other types of body wall repairs that require larger sheets of graft material (column 1 lines 60-65). Small intestinal tissue is taught as the source of the submucosal tissue (column 3 lines 26-27). Patel also teaches that advantageously, both the heterolaminar and homolaminar large area sheets of submucosal tissue have enhanced mechanical strength and have a greater surface area than any one of the individual strips used to form the submucosal sheets (column 5 lines 18-23).

Therefore, one of ordinary skill in the art would have been motivated to use the invention of Badylak ('637) for the repair of the abdominal wall because Patel teaches that a multilayered submucosal graft can be used in hernia repair and other applications that would include the abdominal wall and because Badylak ('637) also teaches that liver basement membrane can be used in most, if not all, of the applications previously reported for intestinal submucosa, including enhancing wound healing, promoting endogenous tissue growth, stimulating cell proliferation and inducing cell differentiation (page 1 lines 16-24). One of ordinary skill in the art would have had a reasonable expectation of success because Oliver et al and Butler teach the use of basement membrane in hernia repair (column 5 lines 60-65).

In addition, one of ordinary skill in the art would have been motivated to use the multilayered homolaminate construct because Patel teaches that both the heterolaminar

and homolaminar large area sheets of submucosal tissue have enhanced mechanical strength and have a greater surface area than any one of the individual strips used to form the submucosal sheets (column 5 lines 18-23) and Badlak ('637) teaches that heterolaminar constructs (those with extra layers at the ends) are preferable for reinforcement for attachment to bone and other structures (page 7 line 2) and thus would not be required when used for abdominal wall repair. A homolaminate construct would be an obvious choice for repair of the abdominal wall repair since attachment to bones, tendons, ligaments, cartilage and muscle would not be required (only attachment to the body wall) and a step would be saved by not having to form the additional layers on the ends as required by the heterolaminar construct. One of ordinary skill in the art would have had a reasonable expectation of success because Badylak ('637) teaches that the liver basement graft composition can be formed in a variety of shapes and configurations (page 6 line 28).

Therefore, the combined teachings of Badylak, Patel, Butler and Oliver et al render obvious Applicant's invention as claimed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 7,482,025 in view of Patel et al (US 5,955,110), Badylak (WO 98/25637), Butler (WO 03/084410) and Oliver et al (US 4,399,123).

Although the conflicting claims are not identical, they are not patentable distinct from each other because the patented claim is drawn to a method for inducing the formation of endogenous tissue at a site in need in a warm-blooded vertebrate comprising implanting a graft composition comprising gelled liver basement membrane tissue of a warm-blooded vertebrate at the site in need in an amount effective and further comprises a glycoprotein.

The ‘025 Patent does not include wherein the body wall or abdominal wall is the site of repair or wherein the construct is multilayered, the thickness of the layers or wherein the construct is formed as a homolaminate. Wherein the construct is in a sheet form and surgically implanted or in powder form is also not included.

Patel teaches a multilayered submucosal graft construct for use in hernia repair, gastroschisis repair (congenital stomach defects) and other types of body wall repairs that require larger sheets of graft material (column 1 lines 60-65). Small intestinal tissue is taught as the source of the submucosal tissue (column 3 lines 26-27). Patel also teaches that advantageously, both the heterolaminar and homolaminar large area sheets of submucosal tissue have enhanced mechanical strength and have a greater surface area than any one of the individual strips used to form the submucosal sheets (column 5 lines 18-23).

Badylak ('637) teaches the use of tissue graft composition comprising liver basement membranes of a warm-blooded vertebrate for the repair of damaged or diseased tissues (page 2 lines 1-6). The graft composition can be implanted or fluidized and injected into a host to contact damaged or defective tissues and induce repair or replacement of the tissues (page 2 lines 6-8). Wherein the composition is in the form of a powder (page 4 line 22), sheet or gel (page 10 lines 20-21) is taught as well as wherein the composition is in a multilayered configuration (page 6 line 31) with sheets or strips having a thickness of up to about 500 μ (page 17 line 14). Badylak ('637) also teaches that basement membrane prepared from liver tissue of warm-blooded vertebrates exhibit certain mechanical and biotropic properties similar to that which had been reported for intestinal submucosal tissue. The reference also states that liver basement membrane can be substituted in most, if not all, of the applications previously reported for intestinal submucosa, including enhancing wound healing, promoting endogenous tissue growth, stimulating cell proliferation and inducing cell differentiation

(page 1 lines 16-24). These applications would all be required for the repair of the body wall. Wherein the construct is taught to have multiple layers at the opposite ends (thus forming a heterolaminate construct) to provide reinforcement for attachment to physiological structures such as bone, tendon, ligament, cartilage and muscle (page 6 line 32- page 7 line 4) is also taught to be an optional embodiment since the liver basement graft composition can be formed in a variety of shapes and configurations (page 6 line 28). The reference includes wherein growth factors and glycoproteins that facilitate cellular proliferation are added to the composition (page 11 lines 16-20).

Oliver et al teach a method wherein basement membrane is used various branches of surgery for the treatment of hernias (column 1 lines 55-66 and column 5 lines 60-62).

Butler teaches that basement membrane is a suitable material for repair of body wall tissues such as hernias (paragraphs 16, 21, 76-84, on pages 8, 10, 30-33).

Therefore, one of ordinary skill in the art would have been motivated to use the method of the copending application for the repair of the abdominal wall because Patel teaches that a multilayered submucosal graft can be used in hernia repair and other applications that would include the abdominal wall and because Badylak ('637) also teaches that liver basement membrane can be used in most, if not all, of the applications previously reported for intestinal submucosa, including enhancing wound healing, promoting endogenous tissue growth, stimulating cell proliferation and inducing cell differentiation (page 1 lines 16-24). One of ordinary skill in the art would have had a reasonable expectation of success because Badylak ('637) reports that basement

membranes prepared from liver tissue of warm-blooded vertebrates exhibit certain mechanical and biotropic properties similar to that which had been reported for intestinal submucosal tissue (page 1 lines 15-20) and Butler teaches that basement membrane is a suitable material for the repair of the body wall.

In addition, one of ordinary skill in the art would have been motivated to use the multilayered homolaminate construct because Patel teaches that both the heterolaminar and homolaminar large area sheets of submucosal tissue have enhanced mechanical strength and have a greater surface area than any one of the individual strips used to form the submucosal sheets (column 5 lines 18-23) and Badylak ('637) teaches that heterolaminar constructs (those with extra layers at the ends) are preferable for reinforcement for attachment to bone and other structures (page 7 line 2) and thus would not be required when used for abdominal wall repair. A homolaminate construct would be an obvious choice for repair of the abdominal wall repair since attachment to bones, tendons, ligaments, cartilage and muscle would not be required (only attachment to the body wall) and a step would be saved by not having to form the additional layers on the ends as required by the heterolaminar construct. The use of different forms such as multilayered, powder and sheet would have been obvious to include in the copending application because Badylak and Patel teach that these are suitable forms for the construct. The thickness of the layers of the construct would have been a matter of routine optimization depending on the thickness of the body wall in need of repair. One of ordinary skill in the art would have had a reasonable expectation of success because

Badylak ('637) teaches that the liver basement graft composition can be formed in a variety of shapes and configurations (page 6 line 28).

Therefore, the combined teachings of the patented claims and Badylak, Patel, Butler and Oliver et al render obvious Applicant's invention as claimed.

Claims 1-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 9 of U.S. Patent No. 6,793,939 in view of Patel et al (US 5,955,110), Badylak (WO 98/25637), Butler (WO 03/084410) and Oliver et al (US 4,399,123).

Although the conflicting claims are not identical, they are not patentable distinct from each other because the patent is drawn to a method for inducing the formation of endogenous tissue at a site in need in a warm-blooded vertebrate comprising implanting a graft composition comprising an extracellular matrix consisting essentially of basement membrane of liver tissue of a warm blooded vertebrate in an amount effective to induce endogenous tissue growth at the site of administration. Wherein the basement membrane is fluidized and administered by injection and administered by surgically implanting and wherein the liver tissue is in sheets having a thickness of up to about 500 μ are also included.

The claims of the patent do not include wherein the body wall or abdominal wall is the site of repair or wherein the construct is multilayered, or wherein the construct is

formed as a homolaminate. Wherein the construct is in a sheet form and surgically implanted or in powder form is also not included.

Patel teaches a multilayered submucosal graft construct for use in hernia repair, gastroschisis repair (congenital stomach defects) and other types of body wall repairs that require larger sheets of graft material (column 1 lines 60-65). Small intestinal tissue is taught as the source of the submucosal tissue (column 3 lines 26-27). Patel also teaches that advantageously, both the heterolaminar and homolaminar large area sheets of submucosal tissue have enhanced mechanical strength and have a greater surface area than any one of the individual strips used to form the submucosal sheets (column 5 lines 18-23).

Badylak ('637) teaches the use of tissue graft composition comprising liver basement membranes of a warm-blooded vertebrate for the repair of damaged or diseased tissues (page 2 lines 1-6). The graft composition can be implanted or fluidized and injected into a host to contact damaged or defective tissues and induce repair or replacement of the tissues (page 2 lines 6-8). Wherein the composition is in the form of a powder (page 4 line 22), sheet or gel (page 10 lines 20-21) is taught as well as wherein the composition is in a multilayered configuration (page 6 line 31) with sheets or strips having a thickness of up to about 500 μ (page 17 line 14). Badylak ('637) also teaches that basement membrane prepared from liver tissue of warm-blooded vertebrates exhibit certain mechanical and biotropic properties similar to that which had been reported for intestinal submucosal tissue. The reference also states that liver basement membrane can be substituted in most, if not all, of the applications previously

reported for intestinal submucosa, including enhancing wound healing, promoting endogenous tissue growth, stimulating cell proliferation and inducing cell differentiation (page 1 lines 16-24). These applications would all be required for the repair of the body wall. Wherein the construct is taught to have multiple layers at the opposite ends (thus forming a heterolaminate construct) to provide reinforcement for attachment to physiological structures such as bone, tendon, ligament, cartilage and muscle (page 6 line 32- page 7 line 4) is also taught to be an optional embodiment since the liver basement graft composition can be formed in a variety of shapes and configurations (page 6 line 28). The reference includes wherein growth factors and glycoproteins that facilitate cellular proliferation are added to the composition (page 11 lines 16-20).

Oliver et al teach a method wherein basement membrane is used various branches of surgery for the treatment of hernias (column 1 lines 55-66 and column 5 lines 60-62).

Butler teaches that basement membrane is a suitable material for repair of body wall tissues such as hernias (paragraphs 16, 21, 76-84, on pages 8, 10, 30-33).

Therefore, one of ordinary skill in the art would have been motivated to use the method of the patent for the repair of the abdominal wall because Patel teaches that a multilayered submucosal graft can be used in hernia repair and other applications that would include the abdominal wall and because Badylak ('637) also teaches that liver basement membrane can be used in most, if not all, of the applications previously reported for intestinal submucosa, including enhancing wound healing, promoting endogenous tissue growth, stimulating cell proliferation and inducing cell differentiation

(page 1 lines 16-24). One of ordinary skill in the art would have had a reasonable expectation of success because Badylak ('637) reports that basement membranes prepared from liver tissue of warm-blooded vertebrates exhibit certain mechanical and biotropic properties similar to that which had been reported for intestinal submucosal tissue (page 1 lines 15-20) and Butler teaches that basement membrane is suitable for repair of the body wall as well.

In addition, one of ordinary skill in the art would have been motivated to use the multilayered homolaminate construct because Patel teaches that both the heterolaminar and homolaminar large area sheets of submucosal tissue have enhanced mechanical strength and have a greater surface area than any one of the individual strips used to form the submucosal sheets (column 5 lines 18-23) and Badylak ('637) teaches that heterolaminar constructs (those with extra layers at the ends) are preferable for reinforcement for attachment to bone and other structures (page 7 line 2) and thus would not be required when used for abdominal wall repair. A homolaminate construct would be an obvious choice for repair of the abdominal wall repair since attachment to bones, tendons, ligaments, cartilage and muscle would not be required (only attachment to the body wall) and a step would be saved by not having to form the additional layers on the ends as required by the heterolaminar construct. The use of different forms such as multilayered, powder and sheet would have been obvious to include in the copending application because Badylak and Patel teach that these are suitable forms for the construct. One of ordinary skill in the art would have had a reasonable expectation of

success because Badylak ('637) teaches that the liver basement graft composition can be formed in a variety of shapes and configurations (page 6 line 28).

One of ordinary skill in the art would have been motivated with a reasonable expectation of success in adding glycoproteins to the basement membrane composition as Badylak ('637) suggest that these facilitate cellular proliferation (page 11).

Therefore, the combined teachings of the patent claims and Badylak, Patel, Butler and Oliver et al render obvious Applicant's invention as claimed.

Response to Arguments

Applicant's arguments filed 08/03/2009 have been fully considered but they are not persuasive.

Applicant argues that the references do not suggest the specific element of removing endotoxins from the graft compositions and thus do not render obvious the claimed invention.

This is not found persuasive because the WO 98/25637 document specifically states that the process of removing the cellular elements from the tissue allows the preparation of a graft composition that is non-immunogenic, and thus does not induce a host immune response when implanted into a host (page 3 lines 3-10). Clearly this process would also remove any endotoxins as well as they would also elicit an immune response if left with the tissue. Applicant's disclosure also suggests that the process of removing the cellular components also removes the endotoxins as well

(page 4 lines 18-25 of the as filed specification). The reference process involves the removal of cells and cellular components from the liver tissue (page 3 lines 3-32) and since this includes the same method steps as taught in the instant application for the removal of DNA and endotoxins (page 4 of the specification) this reference process will also remove DNA and endotoxins as well (page 3 lines 3-32).

Applicant argues that the'123 patent can not be properly combined with the WO 98/25637 document because the '123 patent teaches the removal of the glycoproteins and thus teaches away from the WO 98/25637 and the current claimed invention which require glycoproteins.

This is not found persuasive because the WO 98/25637 teaches enzymatic cell removal steps (page 4) and extraction steps (page 5) that also removes glycoproteins, but also states that proteins, including glycoproteins, that facilitate cellular proliferation can be added back into the basement composition (page 11 lines 16-20). The '123 patent only suggests the removal of those glycoproteins that would cause an antigenic response, not that glycoproteins could not be added back in to the composition as suggested by WO 98/25637. Clearly this demonstrates that many antigenic components (cells, glycoproteins, growth factors) are removed during the preparation of the basement membrane and then new components added back in a form more suitable for the intended method of repair. Therefore the reference teachings are compatible for combination as the '123 patent does not require that glycoproteins that do not elicit an immune response (such as those added back into the composition as taught by WO 98/25637) be absent from the final composition. In addition the teaching of Butler further

demonstrates that basement membrane was known in the prior art to be a suitable material for the repair of the body wall as well.

Applicant's arguments with regard to the double patenting rejections are identical to those presented above and are therefore also not found persuasive as well.

Therefore the claims remain rejected as obvious over the prior art..

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Schuberg whose telephone number is (571)272-3347. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura Schuberg

/JON P WEBER/
Supervisory Patent Examiner, Art Unit 1657